

Environmental Protection Agency

§ 25.1

on the administrative record. If the Presiding Officer finds that any contested relief provision in the order is not supported by a preponderance of the evidence in the record, the Presiding Officer shall recommend that the order be modified and issued on terms that are supported by the record, or withdrawn.

(b) At any time within twenty-one (21) days of service of the recommended decision on the parties, the parties may file comments on the recommended decision with the Clerk. The Clerk shall promptly transmit any such comments received to the Regional Administrator for his consideration in reaching a final decision.

Subpart D—Post-Hearing Procedures

§ 24.18 Final decision.

As soon as practicable after receipt of the recommended decision, the Regional Administrator will either sign or modify such recommended decision, and issue it as a final decision. If the Regional Administrator modifies the recommended decision, he shall insure that the final decision indicates the legal and factual basis for the decision as modified. The Regional Administrator's decision shall be based on the administrative record.

§ 24.19 Final order.

If the Regional Administrator does not adopt portions of the initial order, or finds that modification of the order is necessary, the signatory official on the initial administrative order shall modify the order in accordance with the terms of the final decision and file and serve a copy of the final administrative order. If the Regional Administrator finds the initial order appropriate as originally issued, the final decision shall declare the initial administrative order to be a final order, effective upon service of the final decision. If the Regional Administrator declares that the initial order must be withdrawn, the signatory official on the initial administrative order will file and serve a withdrawal of the initial administrative order. This may be done without prejudice.

§ 24.20 Final agency action.

The final decision and the final administrative order are final agency actions that are effective on filing and service. These actions are not appealable to the Administrator.

PART 25—PUBLIC PARTICIPATION IN PROGRAMS UNDER THE RESOURCE CONSERVATION AND RECOVERY ACT, THE SAFE DRINKING WATER ACT, AND THE CLEAN WATER ACT

Sec.

- 25.1 Introduction.
- 25.2 Scope.
- 25.3 Policy and objectives.
- 25.4 Information, notification, and consultation responsibilities.
- 25.5 Public hearings.
- 25.6 Public meetings.
- 25.7 Advisory groups.
- 25.8 Responsiveness summaries.
- 25.9 Permit enforcement.
- 25.10 Rulemaking.
- 25.11 Work elements in financial assistance agreements.
- 25.12 Assuring compliance with public participation requirements.
- 25.13 Coordination and non-duplication.
- 25.14 Termination of reporting requirements.

AUTHORITY: Sec. 101(e), Clean Water Act, as amended (33 U.S.C. 1251(e)); sec. 7004(b), Resource Conservation and Recovery Act (42 U.S.C. 6974(b)); sec. 1450(a)(1), Safe Drinking Water Act, as amended (42 U.S.C. 300j-9).

SOURCE: 44 FR 10292, Feb. 16, 1979, unless otherwise noted.

§ 25.1 Introduction.

This part sets forth minimum requirements and suggested program elements for public participation in activities under the Clean Water Act (Pub. L. 95-217), the Resource Conservation and Recovery Act (Pub. L. 94-580), and the Safe Drinking Water Act (Pub. L. 93-523). The applicability of the requirements of this part is as follows:

(a) Basic requirements and suggested program elements for public information, public notification, and public consultation are set forth in § 25.4. These requirements are intended to foster public awareness and open processes of government decisionmaking.

§ 25.2

40 CFR Ch. I (7–1–05 Edition)

They are applicable to all covered activities and programs described in § 25.2(a).

(b) Requirements and suggested program elements which govern the structure of particular public participation mechanisms (for example, advisory groups and responsiveness summaries) are set forth in §§ 25.5, 25.6, 25.7, and 25.8. This part does not mandate the use of these public participation mechanisms. It does, however, set requirements which those responsible for implementing the mechanisms must follow if the mechanisms are required elsewhere in this chapter.

(c) Requirements which apply to Federal financial assistance programs (grants and cooperative agreements) under the three acts are set forth in §§ 25.10 and 25.12(a).

(d) Requirements for public involvement which apply to specific activities are set forth in § 25.9 (Permit enforcement), § 25.10 (Rulemaking), and § 25.12 (Assuring compliance with requirements).

§ 25.2 Scope.

(a) The activities under the three Acts which are covered by this part are:

(1) EPA rulemaking, except non-policy rulemaking (for example publication of funding allotments under statutory formulas); and State rulemaking under the Clean Water Act and Resource Conservation and Recovery Act;

(2) EPA issuance and modification of permits, and enforcement of permits as delineated by § 25.9;

(3) Development by EPA of major informational materials, such as citizen guides or handbooks, which are expected to be used over several years and which are intended to be widely distributed to the public;

(4) Development by EPA of strategy and policy guidance memoranda when a Deputy Assistant Administrator determines it to be appropriate;

(5) Development and implementation of plans, programs, standards, construction, and other activities supported with EPA financial assistance (grants and cooperative agreements) to State, interstate, regional and local agencies (herein after referred to as

“State, interstate, and substate agencies”);

(6) The process by which EPA makes a determination regarding approval of State administration of the Construction Grants program in lieu of Federal administration; and the administration of the Construction Grants Program by the State after EPA approval;

(7) The process by which EPA makes a determination regarding approval of State administration of the following programs in lieu of Federal administration: The State Hazardous Waste Program; the NPDES Permit Program; the Dredge and Fill Permit Program; and the Underground Injection Control Program;

(8) Other activities which the Assistant Administrator for Water and Waste Management, the Assistant Administrator for Enforcement, or any EPA Regional Administrator deems appropriate in view of the Agency’s responsibility to involve the public in significant decisions.

(b) Activities which are not covered by this part, except as otherwise provided under (a)(8) or (c) of this section, are activities under parts 33 (Subagreements), 39 (Loan Guarantees for Construction of Treatment Works), 40 (Research and Development Grants), 45 (Training Grants and Manpower Forecasting) and 46 (Fellowships) of this chapter.

(c) Some programs covered by these regulations contain further provisions concerning public participation. These are found elsewhere in this chapter in provisions which apply to the program of interest. Regulations which govern the use and release of public information are set forth in part 2 of this chapter.

(d) Specific provisions of court orders which conflict with requirements of this part, such as court-established timetables, shall take precedence over the provisions in this part.

(e) Where the State undertakes functions in the construction grants program, the State shall be responsible for meeting these requirements for public participation, and any applicable public participation requirements found elsewhere in this chapter, to the same extent as EPA.

(f) Where the State undertakes functions in those programs specifically cited in §25.2(a)(7), the State shall be responsible for meeting the requirements for public participation included in the applicable regulations governing those State programs. The requirements for public participation in State Hazardous Waste Programs, Dredge and Fill Permit programs, Underground Injection Control programs and NPDES permit programs are found in part 123 of this chapter. These regulations embody the substantive requirements of this part.

(g) These regulations apply to the activities of all agencies receiving EPA financial assistance which is awarded after [the effective date of final regulations], and to all other covered activities of EPA, State, interstate, and substate agencies which occur after that date. These regulations will apply to ongoing grants or other covered activities upon any significant change in the activity (for example, upon a significant proposed increase in project scope of a construction grant). Parts 105 (Public Participation in Water Pollution Control) and 249 (Public Participation in Solid Waste Management) will no longer appear in the Code of Federal Regulations; however, they will remain applicable, in uncodified form, to grants awarded prior to the effective date of this part and to all other ongoing activities.

§ 25.3 Policy and objectives.

(a) EPA, State, interstate, and substate agencies carrying out activities described in §25.2(a) shall provide for, encourage, and assist the participation of the public. The term, "the public" in the broadest sense means the people as a whole, the general populace. There are a number of identifiable "segments of the public" which may have a particular interest in a given program or decision. Interested and affected segments of the public may be affected directly by a decision, either beneficially or adversely; they may be affected indirectly; or they may have some other concern about the decision. In addition to private citizens, the public may include, among others, representatives of consumer, environmental, and minority associations; trade, industrial, agri-

cultural, and labor organizations; public health, scientific, and professional societies; civic associations; public officials; and governmental and educational associations.

(b) Public participation is that part of the decision-making process through which responsible officials become aware of public attitudes by providing ample opportunity for interested and affected parties to communicate their views. Public participation includes providing access to the decision-making process, seeking input from and conducting dialogue with the public, assimilating public viewpoints and preferences, and demonstrating that those viewpoints and preferences have been considered by the decision-making official. Disagreement on significant issues is to be expected among government agencies and the diverse groups interested in and affected by public policy decisions. Public agencies should encourage full presentation of issues at an early stage so that they can be resolved and timely decisions can be made. In the course of this process, responsible officials should make special efforts to encourage and assist participation by citizens representing themselves and by others whose resources and access to decision-making may be relatively limited.

(c) The following are the objectives of EPA, State, interstate, and substate agencies in carrying out activities covered by this part:

(1) To assure that the public has the opportunity to understand official programs and proposed actions, and that the government fully considers the public's concerns;

(2) To assure that the government does not make any significant decision on any activity covered by this part without consulting interested and affected segments of the public;

(3) To assure that government action is as responsive as possible to public concerns;

(4) To encourage public involvement in implementing environmental laws;

(5) To keep the public informed about significant issues and proposed project or program changes as they arise;

(6) To foster a spirit of openness and mutual trust among EPA, States, substate agencies and the public; and

§ 25.4

40 CFR Ch. I (7–1–05 Edition)

(7) To use all feasible means to create opportunities for public participation, and to stimulate and support participation.

§ 25.4 Information, notification, and consultation responsibilities.

(a) *General.* EPA, State, interstate, and substate agencies shall conduct a continuing program for public information and participation in the development and implementation of activities covered by this part. This program shall meet the following requirements:

(b) *Information and assistance requirements.* (1) Providing information to the public is a necessary prerequisite to meaningful, active public involvement. Agencies shall design informational activities to encourage and facilitate the public's participation in all significant decisions covered by § 25.2(a), particularly where alternative courses of action are proposed.

(2) Each agency shall provide the public with continuing policy, program, and technical information and assistance beginning at the earliest practicable time. Informational materials shall highlight significant issues that will be the subject of decision-making. Whenever possible, consistent with applicable statutory requirements, the social, economic, and environmental consequences of proposed decisions shall be clearly stated in such material. Each agency shall identify segments of the public likely to be affected by agency decisions and should consider targeting informational materials toward them (in addition to the materials directed toward the general public). Lengthy documents and complex technical materials that relate to significant decisions should be summarized for public and media uses. Fact sheets, news releases, newsletters, and other similar publications may be used to provide notice that materials are available and to facilitate public understanding of more complex documents, but shall not be a substitute for public access to the full documents.

(3) Each agency shall provide one or more central collections of reports, studies, plans, and other documents relating to controversial issues or significant decisions in a convenient location or locations, for example, in public li-

braries. Examples of such documents are catalogs of documents available from the agency, grant applications, fact sheets on permits and permit applications, permits, effluent discharge information, and compliance schedule reports. Copying facilities at reasonable cost should be available at the depositories.

(4) Whenever possible, agencies shall provide copies of documents of interest to the public free of charge. Charges for copies should not exceed prevailing commercial copying costs. EPA requirements governing charges for information and documents provided to the public in response to requests made under the Freedom of Information Act are set forth in part 2 of this chapter. Consistent with the objectives of § 25.3(b), agencies may reserve their supply of free copies for private citizens and others whose resources are limited.

(5) Each agency shall develop and maintain a list of persons and organizations who have expressed an interest in or may, by the nature of their purposes, activities or members, be affected by or have an interest in any covered activity. Generally, this list will be most useful where subdivided by area of interest or geographic area. Whenever possible, the list should include representatives of the several categories of interests listed under § 25.3(a). Those on the list, or relevant portions if the list is subdivided, shall receive timely and periodic notification of the availability of materials under § 25.4(b)(2).

(c) *Public notification.* Each agency shall notify interested and affected parties, including appropriate portions of the list required by paragraph (b)(5) of this section, and the media in advance of times at which major decisions not covered by notice requirements for public meetings or public hearings are being considered. Generally, notices should include the timetable in which a decision will be reached, the issues under consideration, any alternative courses of action or tentative determinations which the agency has made, a brief listing of the applicable laws or regulations, the location where relevant documents may be reviewed or obtained, identification

Environmental Protection Agency

§ 25.5

of any associated public participation opportunities such as workshops or meetings, the name of an individual to contact for additional information, and any other appropriate information. All advance notifications under this paragraph must be provided far enough in advance of agency action to permit time for public response; generally this should not be less than 30 days.

(d) *Public consultation.* For the purposes of this part, “public consultation” means an exchange of views between governmental agencies and interested or affected persons and organizations in order to meet the objectives set forth in § 25.3. Requirements for three common forms of public consultation (public hearings, public meetings, and advisory groups) are set forth in §§ 25.5, 25.6, and 25.7. Other less formal consultation mechanisms may include but are not limited to review groups, ad hoc committees, task forces, workshops, seminars and informal personal communications with individuals and groups. Public consultation must be preceded by timely distribution of information and must occur sufficiently in advance of decision-making to allow the agency to assimilate public views into agency action. EPA, State, interstate, and substate agencies shall provide for early and continuing public consultation in any significant action covered by this part. Merely conferring with the public after an agency decision does not meet this requirement. In addition to holding hearings and meetings as specifically required in this chapter, a hearing or meeting shall be held if EPA, the State, interstate, or substate agency determines that there is significant public interest or that a hearing or meeting would be useful.

(e) *Public information concerning legal proceedings.* EPA, State, interstate, and substate agencies shall provide full and open information on legal proceedings to the extent not inconsistent with court requirements, and where such disclosure would not prejudice the conduct of the litigation. EPA actions with regard to affording opportunities for public comment before the Department of Justice consents to a proposed judgment in an action to enjoin discharges of pollutants into the environ-

ment shall be consistent with the Statement of Policy issued by the Department of Justice (see title 28, CFR, chapter 1, § 50.7).

§ 25.5 Public hearings.

(a) *Applicability.* Any non-adjudicatory public hearing, whether mandatory or discretionary, under the three Acts shall meet the following minimum requirements. These requirements are subordinate to any more stringent requirements found elsewhere in this chapter or otherwise imposed by EPA, State, interstate, or substate agencies. Procedures developed for adjudicatory hearings required by this chapter shall be consistent with the public participation objectives of this part, to the extent practicable.

(b) *Notice.* A notice of each hearing shall be well publicized, and shall also be mailed to the appropriate portions of the list of interested and affected parties required by § 25.4(b)(5). Except as otherwise specifically provided elsewhere in this chapter, these actions must occur at least 45 days prior to the date of the hearing. However, where EPA determines that there are no substantial documents which must be reviewed for effective hearing participation and that there are no complex or controversial matters to be addressed by the hearing, the notice requirement may be reduced to no less than 30 days. EPA may further reduce or waive the hearing notice requirement in emergency situations where EPA determines that there is an imminent danger to public health. To the extent not duplicative, the agency holding the hearing shall also provide informal notice to all interested persons or organizations that request it. The notice shall identify the matters to be discussed at the hearing and shall include or be accompanied by a discussion of the agency’s tentative determination on major issues (if any), information on the availability of a bibliography of relevant materials (if deemed appropriate), and procedures for obtaining further information. Reports, documents and data relevant to the discussion at the public hearing shall be available to the public at least 30 days before the hearing. Earlier availability of materials relevant to the hearing

§ 25.6

will further assist public participation and is encouraged where possible.

(c) *Locations and time.* Hearings must be held at times and places which, to the maximum extent feasible, facilitate attendance by the public. Accessibility of public transportation, and use of evening and weekend hearings, should be considered. In the case of actions with Statewide interest, holding more than one hearing should be considered.

(d) *Scheduling presentations.* The agency holding the hearing shall schedule witnesses in advance, when necessary, to ensure maximum participation and allotment of adequate time for all speakers. However, the agency shall reserve some time for unscheduled testimony and may consider reserving blocks of time for major categories of witnesses.

(e) *Conduct of hearing.* The agency holding the hearing shall inform the audience of the issues involved in the decision to be made, the considerations the agency will take into account, the agency's tentative determinations (if any), and the information which is particularly solicited from the public. The agency should consider allowing a question and answer period. Procedures shall not unduly inhibit free expression of views (for example, by onerous written statement requirements or qualification of witnesses beyond minimum identification).

(f) *Record.* The agency holding the hearing shall prepare a transcript, recording or other complete record of public hearing proceedings and make it available at no more than cost to anyone who requests it. A copy of the record shall be available for public review.

§ 25.6 Public meetings.

Public meetings are any assemblies or gathering, (such as conferences, informational sessions, seminars, workshops, or other activities) which the responsible agency intends to be open to anyone wishing to attend. Public meetings are less formal than public hearings. They do not require formal presentations, scheduling of presentations and a record of proceedings. The requirements of § 25.5 (b) and (c) are applicable to public meetings, except

40 CFR Ch. I (7-1-05 Edition)

that the agency holding the meeting may reduce the notice to not less than 30 days if there is good reason that longer notice cannot be provided.

§ 25.7 Advisory groups.

(a) *Applicability.* The requirements of this section on advisory groups shall be met whenever provisions of this chapter require use of an advisory group by State, interstate, or substate agencies involved in activities supported by EPA financial assistance under any of the three Acts.

(b) *Role.* Primary responsibility for decision-making in environmental programs is vested by law in the elected and appointed officials who serve on public bodies and agencies at various levels of government. However, all segments of the public must have the opportunity to participate in environmental quality planning. Accordingly, where EPA identifies a need for continued attention of an informed core group of citizens in relation to activities conducted with EPA financial assistance, program regulations elsewhere in this chapter will require an advisory group to be appointed by the financially assisted agency. Such advisory groups will not be the sole mechanism for public participation, but will complement other mechanisms. They are intended to assist elected or appointed officials with final decision-making responsibility by making recommendations to such officials on important issues. In addition, advisory groups should foster a constructive interchange among the various interests present on the group and enhance the prospect of community acceptance of agency action.

(c) *Membership.* (1) The agency receiving financial assistance shall assure that the advisory group reflects a balance of interests in the affected area. In order to meet this requirement, the assisted agency shall take positive action, in accordance with paragraph (c)(3) of this section, to establish an advisory group which consists of substantially equivalent proportions of the following four groups:

(i) *Private citizens.* No person may be included in this portion of the advisory group who is likely to incur a financial

gain or loss greater than that of an average homeowner, taxpayer or consumer as a result of any action likely to be taken by the assisted agency.

(ii) *Representatives of public interest groups.* A "public interest group" is an organization which reflects a general civic, social, recreational, environmental or public health perspective in the area and which does not directly reflect the economic interests of its membership.

(iii) Public officials.

(iv) Citizens or representatives of organizations with substantial economic interests in the plan or project.

(2) Generally, where the activity has a particular geographic focus, the advisory group shall be made up of persons who are residents of that geographic area.

(3) In order to meet the advisory group membership requirements of paragraph (c)(1) of this section, the assisted agency shall:

(i) Identify public interest groups, economic interests, and public officials who are interested in or affected by the assisted activity.

(ii) Make active efforts to inform citizens in the affected area, and the persons or groups identified under paragraph (c)(3)(i) of this section, of this opportunity for participation on the advisory group. This may include such actions as placing notices or announcements in the newspapers or other media, mailing written notices to interested parties, contacting organizations or individuals directly, requesting organizations to notify their members through meetings, newsletters, or other means.

(iii) Where the membership composition set forth in paragraph (c)(1) of this section is not met after the above actions, the assisted agency shall identify the causative problems and make additional efforts to overcome such problems. For example, the agency should make personal contact with prospective participants to invite their participation.

(iv) Where problems in meeting the membership composition arise, the agency should request advice and assistance from EPA.

(d) The assisted agency shall record the names and mailing addresses of

each member of the advisory group, with the attributes of each in relation to the membership requirements set forth in paragraph (c)(1) of this section, provide a copy to EPA, and make the list available to the public. In the event that the membership requirements set forth in paragraph (c)(1) of this section are not met, the assisted agency shall append to the list a description of its efforts to comply with those requirements and an explanation of the problems which prevented compliance. EPA shall review the agency's efforts to comply and approve the advisory group composition or, if the agency's efforts were inadequate, require additional actions to achieve the required membership composition.

(e) *Responsibilities of the assisted agency.* (1) The assisted agency shall designate a staff contact who will be responsible for day-to-day coordination among the advisory group, the agency, and any agency contractors or consultants. The financial assistance agreement shall include a budget item for this staff contact. Where substantial portions of the assisted agency's responsibilities will be met under contract, the agency shall require a similar designation, and budget specification, of its contractor. In the latter event, the assisted agency does not have to designate a separate staff contact on its own staff, if the Regional Administrator determines that the contractor's designation will result in adequate coordination. The staff contact shall be located in the project area.

(2) The assisted agency has such responsibilities as providing the advisory group with information, identifying issues for the advisory group's consideration, consulting with the advisory group throughout the project, requesting the advisory group's recommendations prior to major decisions, transmitting advisory group recommendations to decision-making officials, and making written responses to any formal recommendation by the advisory group. The agency shall make any such written responses available to the public. To the maximum extent feasible, the assisted agency shall involve the advisory group in the development of the public participation program.

(3) The assisted agency shall identify professional and clerical staff time which the advisory group may depend upon for assistance, and provide the advisory group with an operating budget which may be used for technical assistance and other purposes agreed upon between the advisory group and the agency.

(4) The assisted agency shall establish a system to make costs of reasonable out-of-pocket expenses of advisory group participation available to group members. Time away from work need not be reimbursed; however, assisted agencies are encouraged to schedule meetings at times and places which will not require members to leave their jobs to attend.

(f) *Advisory group responsibilities and duties.* The advisory group may select its own chairperson, adopt its own rules of order, and schedule and conduct its own meetings. Advisory group meetings shall be announced well in advance and shall be open to the public. At all meetings, the advisory group shall provide opportunity for public comment. Any minutes of advisory group meetings and recommendations to the assisted agency shall be available to the public. The advisory group should monitor the progress of the project and become familiar with issues relevant to project development. In the event the assisted agency and the advisory group agree that the advisory group will assume public participation responsibilities, the group should undertake those responsibilities promptly. The advisory group should make written recommendations directly to the assisted agency and to responsible decision-making officials on major decisions (including approval of the public participation program) and respond to any requests from the agency or decision-making officials for recommendations. The advisory group should remain aware of community attitudes and responses to issues as they arise. As part of this effort, the advisory group may, within the limitations of available resources, conduct public participation activities in conjunction with the assisted agency; solicit outside advice; and establish, in conjunction with the assisted agency, subcommittees, ad hoc groups, or task

forces to investigate and develop recommendations on particular issues as they arise. The advisory group should undertake its responsibilities fully and promptly in accordance with the policies and requirements of this part. Nothing shall preclude the right of the advisory group from requesting EPA to perform an evaluation of the assisted agency's compliance with the requirements of this part.

(g) *Training and assistance.* EPA will promptly provide appropriate written guidance and project information to the newly formed advisory group and may provide advice and assistance to the group throughout the life of the project. EPA will develop and, in conjunction with the State or assisted agency, carry out a program to provide a training session for the advisory group, and appropriate assisted agency representatives, promptly after the advisory group is formed. The assisted agency shall provide additional needed information or assistance to the advisory group.

§ 25.8 Responsiveness summaries.

Each agency which conducts any activities required under this part shall prepare a Responsiveness Summary at specific decision points as specified in program regulations or in the approved public participation work plan. Responsiveness Summaries are also required for rulemaking activities under § 25.10. Each Responsiveness Summary shall identify the public participation activity conducted; describe the matters on which the public was consulted; summarize the public's views, significant comments, criticisms and suggestions; and set forth the agency's specific responses in terms of modifications of the proposed action or an explanation for rejection of proposals made by the public. Responsiveness Summaries prepared by agencies receiving EPA financial assistance shall also include evaluations by the agency of the effectiveness of the public participation program. Assisted agencies shall request such evaluations from any advisory group and provide an opportunity for other participating members of the public to contribute to the evaluation. (In the case of programs with multiple responsiveness summary

requirements, these analyses need only be prepared and submitted with the final summary required.) Responsiveness summaries shall be forwarded to the appropriate decision-making official and shall be made available to the public. Responsiveness Summaries shall be used as part of evaluations required under this part or elsewhere in this chapter.

§ 25.9 Permit enforcement.

Each agency administering a permit program shall develop internal procedures for receiving evidence submitted by citizens about permit violations and ensuring that it is properly considered. Public effort in reporting violations shall be encouraged, and the agency shall make available information on reporting procedures. The agency shall investigate alleged violations promptly.

§ 25.10 Rulemaking.

(a) EPA shall invite and consider written comments on proposed and interim regulations from any interested or affected persons and organizations. All such comments shall be part of the public record, and a copy of each comment shall be available for public inspection. EPA will maintain a docket of comments received and any Agency responses. Notices of proposed and interim rulemaking, as well as final rules and regulations, shall be distributed in accordance with § 25.4(c) to interested or affected persons promptly after publication. Each notice shall include information as to the availability of the full texts of rules and regulations (where these are not set forth in the notice itself) and places where copying facilities are available at reasonable cost to the public. Under Executive Order 12044 (March 23, 1978), further EPA guidance will be issued concerning public participation in EPA rulemaking. A Responsiveness Summary shall be published as part of the preamble to interim and final regulations. In addition to providing opportunity for written comments on proposed and interim regulations, EPA may choose to hold a public hearing.

(b) State rulemaking specified in § 25.2(a)(1) shall be in accord with the requirements of paragraph (a) of this

section or with the State's administrative procedures act, if one exists. However, in the event of conflict between a provision of paragraph (a) of this section and a provision of a State's administrative procedures act, the State's law shall apply.

§ 25.11 Work elements in financial assistance agreements.

(a) This section is applicable to activities under § 25.2(a)(5) except as otherwise provided in parts 30 or 35.

(b) Each applicant for EPA financial assistance shall set forth in the application a public participation work plan or work element which reflects how public participation will be provided for, encouraged, and assisted in accordance with this part. This work plan or element shall cover the project period. At a minimum, the work plan or element shall include:

(1) Staff contacts and budget resources to be devoted to public participation by category;

(2) A proposed schedule for public participation activities to impact major decisions, including consultation points where responsiveness summaries will be prepared;

(3) An identification of consultation and information mechanisms to be used;

(4) The segments of the public targeted for involvement.

(c) All reasonable costs of public participation incurred by assisted agencies which are identified in an approved public participation work plan or element, or which are otherwise approved by EPA, shall be eligible for financial assistance.

(d) The work plan or element may be revised as necessary throughout the project period with approval of the Regional Administrator.

§ 25.12 Assuring compliance with public participation requirements.

(a) *Financial assistance programs—(1) Applications.* EPA shall review the public participation work plan (or, if no work plan is required by this chapter for the particular financial assistance agreement, the public participation element) included in the application to determine consistency with all policies

and requirements of this part. No financial assistance shall be awarded unless EPA is satisfied that the public participation policies and requirements of this part and, any applicable public participation requirements found elsewhere in this chapter, will be met.

(2) *Compliance*—(i) *Evaluation*. EPA shall evaluate compliance with public participation requirements using the work plan, responsiveness summary, and other available information. EPA will judge the adequacy of the public participation effort in relation to the objectives and requirements of § 25.3 and § 25.4 and other applicable requirements. In conducting this evaluation, EPA may request additional information from the assisted agency, including records of hearings and meetings, and may invite public comment on the agency's performance. The evaluation will be undertaken as part of any mid-project review required in various programs under this chapter; where no such review is required the review shall be conducted at an approximate mid-point in continuing EPA oversight activity. EPA may, however, undertake such evaluation at any point in the project period, and will do so whenever it believes that an assisted agency may have failed to meet public participation requirements.

(ii) *Remedial actions*. Whenever EPA determines that an assisted agency has not fully met public participation requirements, EPA shall take actions which it deems appropriate to mitigate the adverse effects of the failure and assure that the failure is not repeated. For ongoing projects, that action shall include, at a minimum, imposing more stringent requirements on the assisted agency for the next budget period or other period of the project (including such actions as more specific output requirements and milestone schedules for output achievement; interim EPA review of public participation activities and materials prepared by the agency, and phased release of funds based on compliance with milestone schedules.) EPA may terminate or suspend part or all financial assistance for non-compliance with public participation requirements, and may take any further actions that it determines to be appropriate in accordance with parts 30

and 35 of this chapter (see, in particular, §§ 30.340, Noncompliance and 30.615-3, Withholding of Payments, and subpart H of part 30, Modification, Suspension, and Termination).

(b) *State programs approved in lieu of Federal programs*. State compliance with applicable public participation requirements in programs specified in § 25.2(a) (6) and (7) and administered by approved States shall be monitored by EPA during the annual review of the State's program, and during any financial or program audit or review of these programs. EPA may withdraw an approved program from a State for failure to comply with applicable public participation requirements.

(c) *Other covered programs*. Assuring compliance with these public participation requirements for programs not covered by paragraphs (a) and (b) of this section is the responsibility of the Administrator of EPA. Citizens with information concerning alleged failures to comply with the public participation requirements should notify the Administrator. The Administrator will assure that instances of alleged non-compliance are promptly investigated and that corrective action is taken where necessary.

§ 25.13 Coordination and non-duplication.

The public participation activities and materials that are required under this part should be coordinated or combined with those of closely related programs or activities wherever this will enhance the economy, the effectiveness, or the timeliness of the effort; enhance the clarity of the issue; and not be detrimental to participation by the widest possible public. Hearings and meetings on the same matter may be held jointly by more than one agency where this does not conflict with the policy of this paragraph. Special efforts shall be made to coordinate public participation procedures under this part and applicable regulations elsewhere in this chapter with environmental assessment and analysis procedures under 40 CFR part 6. EPA encourages interstate agencies in particular to develop combined proceedings for the States concerned.

§ 25.14 Termination of reporting requirements.

All reporting requirements specifically established by this part will terminate on (5 years from date of publication) unless EPA acts to extend the requirements beyond that date.

PART 26—PROTECTION OF HUMAN SUBJECTS

Sec.

- 26.101 To what does this policy apply?
- 26.102 Definitions.
- 26.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
- 26.104–26.106 [Reserved]
- 26.107 IRB membership.
- 26.108 IRB functions and operations.
- 26.109 IRB review of research.
- 26.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 26.111 Criteria for IRB approval of research.
- 26.112 Review by institution.
- 26.113 Suspension or termination of IRB approval of research.
- 26.114 Cooperative research.
- 26.115 IRB records.
- 26.116 General requirements for informed consent.
- 26.117 Documentation of informed consent.
- 26.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 26.119 Research undertaken without the intention of involving human subjects.
- 26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
- 26.121 [Reserved]
- 26.122 Use of Federal funds.
- 26.123 Early termination of research support: Evaluation of applications and proposals.
- 26.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§ 26.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency which takes appropriate administrative action to

make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal department or agency, whether or not it is regulated as defined in § 26.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in § 26.102(e) must be reviewed and approved, in compliance with § 26.101, § 26.102, and § 26.107 through § 26.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic,